IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' GENERAL LIABILITY EXPERTS

All four of Plaintiffs' remaining general liability experts—Mark Kenny, James Farley, David Bliesner, Ph.D., and Russell Somma, Ph.D.—admit they have seen no direct evidence that Actavis released defective Digitek® to the market. None of their reports so much as *mention* "defective" or out-of-specification Digitek®. If these four experts testified consistent with their reports, this litigation would be over.

During their depositions, however, it became clear that all four of these experts intend to testify that Actavis released defective Digitek® to the market. The methodology supporting their conclusions consists of nothing more than: (1) reviewing FDA regulatory documents; (2) assuming—without conducting any Digitek®-specific analysis of the FDA's observations—that the FDA documents accurately indicate that Actavis produced and released to market adulterated (which does not mean out-of-specification or defective) Digitek®; and (3) inferring, again without any Digitek®-specific analysis, that some admittedly undetermined amount of the adulterated Digitek® did not meet specifications *and* was released to consumers.

All four of these experts acknowledge that their methodology is markedly less rigorous than the process they would use if undertaking an identical analysis in a non-litigation context. All testified that they would not or could not reach the conclusions they propose to offer in this

litigation by applying the same methodology that they use in their everyday practice. But despite knowing that adulteration is not the same as defective and admitting that they did not undertake a proper analysis to support their conclusions, these experts nevertheless conclude that Actavis released out-of-specification Digitek®. This testimony violates Rule 702 in a series of ways.

Plaintiffs' experts admit that an adulterated drug is not the same thing as a defective drug.[1] By their own admission, therefore, their opinions will not help a jury to evaluate the essential issue in these products liability cases—defect—as Rule 702 requires. Their opinions should be excluded for this reason alone. But even if adulteration opinions were relevant, the testimony of Plaintiffs' experts is not admissible because Plaintiffs' experts (1) admittedly lack "sufficient facts or data" to support their opinions, and (2) rely instead on an "ipse dixit" methodology that, lacking the same intellectual rigor the experts would apply in their everyday practice, violates the *Daubert* standard.

Additionally, all of Plaintiffs' experts offer "bad company" testimony about Actavis's motives and company ethics, notwithstanding the fact that courts across the country and within

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[1] Defendants have detailed the distinction between a drug that is defective and one that is adulterated in their Memorandum Supporting Defendants' Motion for Summary Judgment. (*See* Doc. 524 at 9-11). Just as evidence of adulteration cannot satisfy Plaintiffs' burden to prove defect, evidence of adulteration cannot support an expert's opinion that Actavis marketed defective product.

Moreover, Plaintiffs' experts were hired to evaluate whether Actavis produced adulterated, not defective, Digitek®. (*See infra* at 8). Accordingly, their reports address only adulteration without ever mentioning defects. To the extent the experts testified about defective Digitek® during their depositions, or intend to do so at trial, their opinions cannot result from a reliable methodology and must be the product of spur-of-the-moment inferences drawn during their deposition from their prior research about adulteration, because none of them applied any methodology aimed at answering the defect question—they were not asked, and did not even try, to answer the question.

this district forbid such testimony. This Court should exclude those opinions even if it otherwise permits Plaintiffs' experts to testify.

SUMMARY OF PLAINTIFFS' EXPERTS' OPINIONS

Four of Plaintiffs' general liability experts remain in this litigation—Mark Kenny, James Farley, David Bliesner, Ph.D., and Russell Somma, Ph.D:

- Mr. Kenny is a mechanical and biomedical engineer who runs a consulting business called SpyGlass Group. (Deposition of Mark Kenny at 8:13-24, 22:22-25, 404:3-13, attached to Defendants' General Background Statement ("Background Statement") as Exhibit 16).

- Mr. Farley, a consultant with Smart Consulting Group, is a chemist who worked with pharmaceutical companies in the fields of research and analytical chemistry. (Deposition of James Farley at 7:7-22, 343:7-347:16, attached to Background Statement as Exhibit 17).

- Dr. Bliesner, an analytical chemist, is the President and founder of Delphi Analytical Services, Inc. (Deposition of David Bliesner, Ph.D. at 156:25-157:12, 265:15-266:20, attached to Background Statement as Exhibit 14).

- And Dr. Somma, a former pharmaceutical engineer, runs his own consulting firm called SommaTech, LLC. (Deposition of Russell Somma, Ph.D. at 12:12-13:20, attached to Background Statement as Exhibit 15).

All four of Plaintiffs' experts offer essentially the same opinions:

- All four experts opine that Digitek® was "adulterated." (Kenny Report at 35, attached as Exhibit A; Farley Report at 19, attached as Exhibit B; Bliesner Report at 21, attached as Exhibit C; Somma Dep. at 182:11-182:25).

- But all four agree that "adulterated" does not mean "defective." (*See* Farley Dep. at 84:10-25; Kenny Dep. at 55:17-56:7; Bliesner Dep. at 27:24-29:4; Somma Dep. at 76:7-23).

- None of the four experts opine in their reports that Actavis produced or released defective or out-of-specification Digitek®. (*See generally* Kenny Report; Farley Report; Bliesner Report; Somma Report, attached as Exhibit D).

- All four concede that there is no direct evidence of defective Digitek® in the market. (*See* Kenny Dep. at 134:10-19; Farley Dep. at 35:18-24; Bliesner Dep. at 443:17-23; Somma Dep. at 157:25-158:4).

- Even though all four testify that they believe out-of-specification product made it to market, not one will testify to a probability that out-of-specification tablets reached the plaintiffs. (Kenny Dep. at 294:20-295:1; Farley Dep. at 453:1-4; Bliesner Dep. at 214:24-215:13; Somma Dep. at 207:12-208:3).

- Additionally, all of Plaintiffs' experts would offer opinions impugning Actavis's knowledge and company ethics, questioning its employees' motives, implying that Actavis employees did not care about product safety, and otherwise speculating about individuals' intent and motives. (*See* Kenny Report at 14-18, 35; Farley Report at 21; Bliesner Report at 18-19, Somma Report at 13).

The vast majority of the FDA documents on which the experts rely do not pertain to Digitek®, and those that do have nothing to do with Digitek® size or content specifications. (*See* Background Statement at 17-20). From these documents, the experts infer that Actavis manufactured and released "adulterated" Digitek®. And while all four experts acknowledge that adulteration and defect are not the same, each one nevertheless infers that if Actavis marketed adulterated Digitek®, it must have marketed *defective* Digitek®. This is not a conclusion they can reliably make.

LAW AND ARGUMENT

A. The Rule 702 Standard Ensures That Courts Admit Only Relevant and Reliable Testimony Offered by Qualified Experts.

Federal Rule of Evidence 702 governs the admission of expert testimony:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Rule 702 imposes a gatekeeping function on the trial judge to determine not only whether a purported expert is qualified to opine in a particular discipline, *see Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 477 (M.D.N.C. 2006), but also whether an opinion is relevant and reliable, *see Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588 (1993)

(mandating that a trial court "ensure that any and all scientific testimony . . . is not only relevant, but reliable."). Within the text of Rule 702 are four different requirements that Plaintiffs must satisfy before their experts may testify—(1) qualifications, (2) sufficient facts or data, (3) reliable principles and methodologies, and (4) relevance to the facts of the case.

Rule 702 is especially pivotal for these Plaintiffs because their claims rely on complex manufacturing and regulatory issues concerning a prescription drug product, making expert testimony an essential aspect of their case. If this Court grants Defendants' Motion to Exclude, then Plaintiffs have failed to meet their burden of proof. That failure of proof, alone, calls for this Court to enter judgment in Defendants' favor. *See, e.g.*, *Am. Cyanamid Co. v. St. Louis University*, 336 F.3d 307, 310-11 (4th Cir. 2003) (affirming summary judgment because plaintiffs failed to present any expert testimony in support of an essential element of a products liability claim against vaccine manufacturer); *Samuel v. Ford Motor Co.*, 112 F. Supp. 2d 460, 467-68 (D. Md. 2000) ("When expert testimony is needed to prove an essential element of a claim, such as causation-as often is the case in medical malpractice or products liability cases-then issues regarding the admissibility of the expert's testimony, and its ultimate effect on whether the plaintiff succeeds in meeting his or her burden of proof, can become intertwined.").

1. Only "qualified" experts may testify under Rule 702.

To qualify a witness as an expert, the party proffering that witness must establish that the witness has sufficient knowledge, experience, training, or education to testify under Rule 702. *See Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). Moreover, "[u]nless he is to testify only to general principles that any [person in the profession] would know," the expert "must possess 'some special skill, knowledge, or experience,' concerning the particular issue before the court." *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 393 (D. Md. 2001).

2. An expert's opinions must be "based upon sufficient facts or data."

After qualifications, the first question posed by Rule 702 is whether a proposed expert's testimony is "based upon sufficient facts or data." *See* Fed. R. Evid. 702. This inquiry is not only part of the "reliability" prong of *Daubert*, but also its own independent requirement apart from a reliable methodology. An expert's opinion cannot be considered reliable if there was an insufficient factual basis for the expert's opinions, no matter what methodological approach the expert takes. *See Fernandez v. Spar Tek Indus., Inc.*, No. 0:06-3253-CMC, 2008 WL 2185395, at *6 (D.S.C. May 23, 2008) ("It follows [from Rule 702] that an opinion based on an inadequate or inaccurate factual foundation cannot be a reliable opinion, no matter how valid the principles and methods applied or how well-qualified the expert.").

3. An expert's opinions must be derived from a reliable methodology.

Courts within the Fourth Circuit interpret *Daubert* to "command[] that in court, science must do the speaking, not merely the scientist." *Cavallo v. Star Enterprise*, 892 F. Supp. 756, 761 (E.D. Va. 1995). To enforce this mandate, a trial judge, acting as gatekeeper, must ensure that "the testimony is based on 'scientific knowledge' (i.e. knowledge grounded 'in the methods and procedures of science')." *Maryland Casualty Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 784 (4th Cir. 1998) (citing *Daubert*, 509 U.S. at 590, 592). This is the *Daubert* "reliability" inquiry. And when evaluating reliability, courts within the Fourth Circuit employ a non-exhaustive list of factors ranging from "whether a theory or technique can be or has been tested" to "whether an expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion" and "whether [experts] have developed their opinions expressly for purposes of testifying." *See Ortho-Clinical Diagnostics*, 440 F. Supp. 2d at 470 (collecting cases).

Collectively, the *Daubert* reliability factors focus on the essential requirement that an expert "employ[] in the courtroom the same level of intellectual rigor that an expert in the same field would employ." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); *see also Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). To this end, trial courts must remember "the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("Daubert II"). When an expert prepares an opinion as a paid litigation consultant, the expert must be equally as careful as when the expert develops opinions in his or her regular professional work. *See Cooper*, 259 F.3d at 200; *see also Ortho-Clinical*, 440 F. Supp. 2d at 470. Otherwise, the purported expert's testimony may be excluded for unjustifiably extrapolating from an accepted premise to an unfounded conclusion, such that there is "too great an analytical gap between the existing data and the opinion proffered." *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

4. An expert's testimony must be relevant and "fit" the disputed factual issue.

The Fourth Circuit also requires courts to verify "whether the testimony will be helpful to the trier of fact." *Therm-O-Disc*, 137 F.3d at 784. This inquiry focuses on relevance, or whether testimony "fits" the disputed issues in the case. Accordingly, courts ask "whether expert testimony . . . is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Daubert*, 509 U.S. at 591; *see also United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995) (quoting *Daubert*, 509 U.S. at 590-91). Expert testimony that "does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591.

B. The Experts' "Adulteration" Opinions Are Not Relevant.

Opinions that Actavis marketed adulterated Digitek® are irrelevant, do not "fit" the issues involved in this litigation, and should be excluded for these reasons alone. As Defendants explain in their contemporaneously filed Memorandum in Support of Defendants' Motion for Summary Judgment, it is Plaintiffs' burden to establish that Digitek® was "defective" and they cannot meet that burden with evidence of adulteration. (Doc. 524 at 9-13).

Adulteration does not mean defective and, without more, cannot serve as a basis for proving defect. (*See id.*). This proposition is embraced by the FDA, federal courts across the country, and even Plaintiffs' own experts. (*See id.*; *supra* at 3). For example, Mr. Farley testified that an adulterated drug may still match its specifications (*see* Farley Dep. at 87:10-22), and Dr. Bliesner testified that the adulteration statute, 21 C.F.R. § 351(a)(2)(B), does not address whether a drug is out of specification, dangerous, or defective (*see* Bliesner Dep. at 28:3-29:4).

Evidence of adulteration, in short, "does not relate to any issue" in this litigation, and is, therefore, "non-helpful." *See Daubert*, 509 U.S. at 591. Adulteration is, however, all that Plaintiffs' experts purport to discuss. These experts were retained to review whether Actavis complied with FDA regulations while manufacturing Digitek®. (*See* Kenny Dep. at 292:20-293:2; Bliesner Dep. at 36:9-23). None of their reports go beyond that issue to discuss whether Actavis released out-of-specification Digitek®. (*See* Somma Dep. at 201:14-19; Farley Dep. 361:6-9; Bliesner Dep. at 50:8-51:17). Their testimony about adulteration, therefore, will not bring a fact finder any closer to an answer to the question "did Actavis market defective Digitek®?" and provides no reliable basis from which a juror can conclude defect.

C. Even If Relevant, Plaintiffs' Experts Have Not Reviewed "Sufficient Facts or Data" to Reliably Support Their Conclusions.

1. Plaintiffs' experts have reviewed barely any of the production records for the recalled Digitek®.

Even if the adulteration opinions offered by Plaintiffs' experts were relevant, their opinions should still be excluded because by their own admission, they are not "based upon sufficient facts or data." *See* Fed. R. Evid. 702. Plaintiffs' experts repeatedly explained during their depositions that to properly evaluate whether Actavis manufactured and released adulterated Digitek®, they must review production records for all of the recalled Digitek®. Defendants produced all these records to Plaintiffs. Nevertheless, Plaintiffs' experts testified that they did not review—and in fact were prevented from reviewing—these essential records.

Mark Kenny offers his adulteration opinion having reviewed only three batch records out of 152 batches recalled, despite describing it as "extremely important" and "critical" to review the others. Mr. Kenny, along with his partner Sal Romano, first received documents from Plaintiffs' counsel on February 24, 2010. (Kenny Dep. at 530:12-14). That same day, Mr. Kenny e-mailed Mr. Romano: "the actual batch records are extremely important. Do you want me to request the information?" (*See id.* at 530:15-23; February 24, 2010 E-mail attached as Exhibit E at 2-3).[2] Moments later, Mr. Romano responded to Plaintiffs' counsel: "Mark and I believe the batch records will be critical for us to review. How many batches were recalled? Do you have all the batch records as PDF files? We have lots to read now, but I think we'll have to take a look at the batch records soon." (*See* Kenny Dep. at 530:24-531:6; Exhibit E). Plaintiffs'

[2] Multiple copies of the relevant February 24, 2010 e-mail thread were contained within Defendants' deposition Exhibit 143, a 115 page collection of various e-mails received from Mr. Kenny at his deposition. (Kenny Dep at 527:22-528:2). Defendants submit only the first page of Exhibit 143 and the version of the relevant e-mails that appear at pages 47-48 therein.

counsel replied in the affirmative, but never sent additional records. (Kenny Dep. at 532:4-10). Consequently, Mr. Kenny cannot make any conclusions about the 149 batches of Digitek® for which he did not review records. (*See id.* at 533:10-12).

Similarly, James Farley testified that he did not review for this litigation documents necessary to determine whether a manufacturer produced and released adulterated product. Mr. Farley explained during his deposition that, if hired by a pharmaceutical manufacturer to evaluate "whether [a] product had been manufactured in compliance with Good Manufacturing Practices ["cGMPs"]," he would "want to see all documents associated with production of that product." (*See* Farley Dep. at 17:16-18:19). In fact, he described with specificity the "very important" need to see "the whole workload from raw materials in to finished product out." (*Id.* at 18:11-15). Mr. Farley cannot arrive at a reliable conclusion as to whether Actavis produced and released adulterated Digitek® without first examining all the records:

> Q. Well, and to determine whether [an observation contained on an FDA Form 483] related to any product that's not listed by the investigator you couldn't do that without reviewing batch records for that product, could you?
>
> . . .
>
> A. Yeah. We would have to look at every one.
>
> Q. Every one what?
>
> A. Every product and all the batch records. I would have an idea as to whether it would or not by looking at that as I did look at the 483. But to be sure you'd have to go through each one of them.
>
> Q. And unless you did that you couldn't offer an opinion about whether it actually relates to each product?
>
> A. I could offer an opinion. I just wouldn't be sure of it. (*Id.* at 131:9-25).

Nevertheless, Mr. Farley reviewed only one set of records—for batch 70924, in which 20 double-thick tablets were found during production, but removed before release to market—and

so cannot identify whether any other batches of recalled Digitek® were problematic. (*Id.* at 57:15-58:13).

Dr. Bliesner and Dr. Somma also commit the same methodological mistake. Dr. Bliesner testified that if a client retained him to assess compliance with cGMPs, but refused to give access to production records, he would tell that client that he cannot conduct "a comprehensive, accurate assessment of GMP compliance" without those records. (Bliesner Dep. at 300:17-301:23). Indeed, he agrees that he just "couldn't do" an assessment of the production system without production records. (*Id.* at 301:18-23). As for Dr. Somma, he testified that his audit process typically involves first a review of batch records, and second an examination of process validation reports. (*See* Somma Dep. at 45:11-16). But here, he admittedly remembered reviewing only a few batch records. (*Id.* at 36:7-12). His opinions are drawn almost entirely from three documents—the investigation report for lot 70924 (the same non-conforming lot that Mr. Farley reviewed), the batch record for that lot, and the batch record for lot 71005A. (*See* Somma Report at 7, Somma Dep. at 34:6-35:1).

This Court should find that the opinions expressed by Plaintiffs' experts are unreliable without even delving into their methodology because none of Plaintiffs' experts reviewed more than a handful of the records produced to Plaintiffs. When these purported experts testified that they cannot arrive at an informed and reliable opinion about adulterated Digitek® without first reviewing "every one" (Farley Dep. at 131:15) of the "extremely important" (Kenny Dep. at 530:18-19) records, they set a standard for themselves. In reviewing no more than a handful of records, they fell well short of their own standard. None of their opinions are "based upon sufficient facts or data." *See* Fed. R. Evid. 702.

2. Plaintiffs' experts formed their opinions about adulteration without any Digitek®-specific analysis of the FDA's observations.

There is a simple explanation for why Plaintiffs' experts all agree that they needed to review Digitek®-specific production records. FDA regulatory documents contain "observations" about conditions that the FDA believes are cGMP-deficient and list examples that support each observation, with references to specific products. These observations result from FDA inspectors' review of product-specific records. Plaintiffs' experts concede that if an FDA observation does not reference a specific product, then there is no logical basis for concluding that the cGMP deficiency identified in that observation pertains to that specific product—at least, not without first reviewing the production records for that product to determine whether the issue identified in the observation actually manifests in the records.

Mr. Farley acknowledges that an opinion about whether a product not mentioned in the FDA's observations is in fact adulterated, formed without a product-specific review, is "speculation." (Farley Dep. at 131:9-132:12). He cannot, however, point to any place in the records where the FDA found that Digitek, specifically, was "adulterated" or of sub-standard quality. (*See id.* at 375:11-376:6). Mr. Kenny and his partner confirmed the need for this product-specific review when they told Plaintiffs' counsel that they would "have to take a look at the batch records." (Kenny Dep. at 530:24-531:6). Indeed, Mr. Kenny went so far as to say that even if the FDA observed that there was a "total quality failure," which it did not, he could not reliably conclude that there was out-of-specification Digitek® in consumers' hands. (*See* Kenny Dep. at 228:23-230:5). And Dr. Bliesner acknowledges that even the FDA itself would have to conduct this product-specific review before it could conclude that an unmentioned product was adulterated. (Bliesner Dep. at 454:12-455:16).

Defendants' Background Statement (Doc. 522) demonstrates that there are few specific references to Digitek® among the FDA's observations. A review of those observations establishes that none of them indicate that Actavis released adulterated Digitek® to the market. (*See* Doc. 522 at 17-18). None of Plaintiffs' experts conducted the kind of detailed, product-specific review that would allow them to conclude otherwise. Simply, they have not sorted through which of the "adulterated" observations in the various FDA documents, if any, suggest that Digitek® was adulterated. Accordingly, they lack sufficient facts or data to support an inference that FDA observations pertaining to Actavis products generally, or to other specific products, applies to Digitek®.

3. Plaintiffs' experts formed their opinions about out-of-specification Digitek® without any product testing data.

Just as Plaintiffs' experts agree that Digitek®-specific document analyses are essential to form a basis for an adulteration opinion, they also agree that physical product testing is a critical basis for any reliable opinions about out-of-specification or defective Digitek®. Mr. Farley co-authored a November 2008 article entitled "Discovering the Cause of a Drug's Defect." (attached as Exhibit F). In a section titled "Pre-Filing Investigation," the article addresses the very regulatory issues that these experts confront, adulteration and cGMPs. But instead of only examining regulatory documents, as Plaintiffs' experts did here, the article states that when examining for defects, "[a] laboratory *must analyze the drug and test for* its active pharmaceutical ingredient (API) and for strength and purity." (*Id.* at 3) (emphasis added).

When asked in his deposition whether he agrees with the statement in his article that a laboratory must analyze and test drugs for content, strength, and purity, Mr. Farley confirmed that he advocates the need "to go beyond the regulatory definition of adulteration to testing to find out whether [a drug] is what it purports to be." (Farley Dep. at 363:4-16). When asked

about this statement, Dr. Somma agreed. (Somma Dep. at 81:13-21). So too does Mr. Kenny, although he qualifies that plaintiffs "should" test, not "must." (*See* Kenny Dep. at 93:6-94:1).

Most plaintiffs in this litigation did not test their tablets. Those plaintiffs that did test found that their tablets were within specifications. Consequently, Plaintiffs' experts have no testing data to rely upon. Their agreement as to the importance of product testing directly undermines the reliability of their inferences, unsupported by any such testing, that Actavis released out-of-specification Digitek®. The inadequate basis for their opinions is especially clear in light of the substantial history of unrefuted affirmative product testing conducted on Digitek® by Actavis, FDA, Mylan, and UDL.

D. The Methodology By Which Plaintiffs' Experts Conclude That Actavis Produced and Released "Adulterated" Digitek® Violates Rule 702.

Plaintiffs' experts agree that to evaluate compliance with cGMPs for a specific product—and thus, whether that product is adulterated or not—they need to review all the production records. They have not. This is not only a problem with the factual basis for their opinions, but also with their methodology as a whole. Each of these purported experts has a career as a compliance consultant. When they review compliance for a pharmaceutical manufacturer client, they conduct a comprehensive "audit." Only after following a well-established methodology can they reach an opinion as to whether or not the client violated the FDA's cGMP regulations.

Plaintiffs' experts do not apply the same methodology for this litigation that they would in their roles as consultants for a pharmaceutical manufacturer. Instead of conducting a comprehensive audit, they each admit to omitting crucial steps in the processes they employ in their everyday practice. In lieu of their usual methods, they each make assumptions about Digitek® based only on general regulatory documents that, in the vast majority of instances, discussed products *other* than Digitek®. (*See* Background Statement at 17-20); *see also Lopez v.*

I-Flow, Inc., Nos. CV 08-1063-PHX-SRB, et seq., 2011 WL 1897548, at *10-11 (excluding testimony from Plaintiffs' expert witness who made summary conclusions from regulatory documents without offering any analysis to support her opinions). Worse, they then make *another* inference—one not even included in their reports—that if Actavis released adulterated Digitek®, then it released defective Digitek®.

The experts' conclusions with regard to adulteration are—as described above—irrelevant. But moreover, the inferences by which each expect reaches that opinion are themselves inherently flawed and, piled one on top of the other as they are, cannot support the experts' opinions under Rule 702. *See In re Trasylol Prods. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1737107, at *20 (S.D. Fla. Apr. 27, 2010) (expert's regulatory opinion excluded as unreliable because the broadly written report, stacked inference upon inference, did not satisfy "the opinion constraints" of Rule 702).

Each expert's individual methodology, and why it is so flawed, is discussed below.

1. Mark Kenny did not apply his own methodology.

Mark Kenny's opinions in this litigation lack any intellectual rigor because, rather than apply a tried and tested process, Mr. Kenny merely assumes that statements made in various FDA regulatory documents were true. This is the absence of a methodology; any lay person in Mr. Kenny's position could make the exact same inference.

Mr. Kenny's failure to apply a reliable methodology is unforgiveable here, where he in fact knows of, but chooses not to use, a process for determining when adulterated product is released to the market. He testified that if he were retained to conduct the exact same analysis as a consultant for a pharmaceutical manufacturer, he would engage in a ten-step "audit." (*See* Kenny Dep. at 234:10). He would:

1) Review all of the "non-conformances" to determine whether "there's a reasonable possibility that material would be released to the market";

2) Look at complaints to determine whether consumers received product that had an alleged conformance issue;

3) Examine the applicable batch records;[3]

4) Review the company's preventative maintenance;

5) Review calibration records

6) Review lab notebooks

7) "[G]o into the micro lab" and "take a look at the facility itself";

8) "[G]o through the analytical lab";

9) "[L]ook at the training records of those people that did the tests"; and

10) "[F]ollow through with – on a manufacturing level – all – all the areas I felt that were – could impact on the quality of the product." (*Id.* at 231:19-235:22).

But here, where Mr. Kenny was asked to prepare opinions for litigation, he has *not* conducted the "audit" steps as he ordinarily would for a pharmaceutical company client:

Q. You did not do all of that in this instance; right?

A. I did not, sir.

(*Id.* at 235:23-25). He did not, for example, review all applicable batch records or conduct any physical inspections of the micro lab or analytical lab facilities. (*See id.* at 234:6-235:25). Instead, Mr. Kenny relies solely on the materials he received from Plaintiffs' counsel—materials hand-picked by the Plaintiffs' Steering Committee for their obvious potential to create negative inferences that defective Digitek® was released.

In other words, the methodology Mr. Kenny employed to develop his opinions in this litigation is radically different from the methodology he claims he would employ if hired by a

[3] As explained on pages 9-10, *supra*, Mr. Kenny in fact omits this step from his analysis, despite describing batch record review as an "extremely important" and "critical" step.

pharmaceutical company to determine whether defective product was released to the market. This litigation methodology, which consists of a limited review of a select set of documents provided to him by the Plaintiffs' Steering Committee, is admittedly *less* intellectually rigorous than "an expert in the same field would employ." Based solely on his review of these documents, he has not only inferred that Actavis released adulterated Digitek®, but also formed an "in my heart of hearts" belief that out-of-specification Digitek® reached consumers. This "belief," without more, cannot satisfy a central tenet of *Daubert* and Rule 702, intellectual rigor, which the Supreme Court and the Fourth Circuit have described as *the* "objective of *Daubert*'s gatekeeping requirement." *Kumho Tire*, 526 U.S. at 152; *Cooper*, 259 F.3d at 200. To admit Mr. Kenny's opinion would render the "intellectual rigor" requirement meaningless.

2. James Farley did not apply his own methodology.

James Farley's opinions, like those expressed by Mark Kenny, are inadmissible because the methodology with which he forms an opinion about adulterated Digitek® lacked the same degree of "intellectual rigor" that he would use in the same analysis outside of the litigation context. Mr. Farley testified that if he were retained to advise a pharmaceutical company about "whether a certain product [has] been manufactured and released in compliance with Good Manufacturing Practices," he would conduct an exhaustive review of the company's manufacturing-related documents, "from raw materials coming in, process materials as it is being produced and the testing that's associated with it and the finished goods released." (*See supra* at 10-11; Farley Dep. at 18:6-18:19).

Here, Mr. Farley has not reviewed the documents he deems necessary to form an opinion in his non-litigation consulting role, particularly batch records. Ordinarily, his review process is so comprehensive that Mr. Farley puts everything in writing in order to ensure that his client

does not "try to get [him] to short-cut something." (Farley Dep. at 18:20-19:3). And in fact, Mr. Farley typically would *reject* an engagement if the company would not allow him to conduct a complete review. (*See id.* at 19:7-20:1). But for the purposes of this litigation, Mr. Farley has agreed to provide an opinion about adulterated Digitek notwithstanding the fact that he has reviewed only the batch records for *one* of the 152 recalled batches. That he so willingly allows Plaintiffs' counsel to "short-cut" his analysis by omitting additional batch records or *any* of the Digitek® production records confirms that his for-litigation investigation is in fact less intellectually rigorous than the review he would conduct in his everyday consultant work.

By Mr. Farley's own standard, he should have told Plaintiffs that he could not accept this project. (*See id.* at 19:7-20:1). Instead, he developed an opinion from a far less comprehensive review than he would otherwise undertake. He candidly admits that his opinions were "based on the [FDA] 483s and the warning letters and the consent decree," *not* a systematic review of all batch records. (*Id.* at 451:13-21). He has not tried to verify whether or not batch 70924 was an isolated problem—despite acknowledging that he could, and normally *would* do so by reviewing the records he chose not to review here. (*See id.* at 249:25-250:21). In short, he was less careful preparing opinions for this litigation than he would be in a non-litigation context. Like Mr. Kenny, whose testimony suffers the same problem, Mr. Farley's opinions are inadmissible.

3. David Bliesner did not apply—and is admittedly incapable of applying—a reliable methodology for determining whether Actavis released adulterated Digitek® to market.

David Bliesner's opinion that Actavis produced and released adulterated Digitek® poses two layers of reliability problems. First, Dr. Bliesner admits that although he offers an opinion that Actavis released adulterated Digitek®, he is not capable of and would not in the ordinary course of a standard consulting agreement agree to undertake an analysis of whether adulterated

product reached consumers. And second, Dr. Bliesner admitted during his deposition that the methodology by which he inferred that Actavis even *produced* adulterated Digitek® was not the same as, and was in fact less intellectually rigorous than, the methodology he would apply if he was conducting the same analysis as a consultant for a pharmaceutical manufacturer.

Put simply, Dr. Bliesner lacks any methodology with which to support his opinion that Actavis *released* adulterated Digitek® to consumers. He admits that opinions as to whether Actavis released adulterated product to market are beyond his expertise or capabilities. Indeed, if he was engaged by a client to determine whether adulterated or defective product made it to market, he would refuse to undertake the analysis or offer a conclusion:

> A. . . . [A]s I said before, I'm not a recall expert. So I would source somebody in my consulting chain who is an expert in investigating products on the market that may be adulterated and has done recalls. I would not do – undertake that myself. It's not my expertise.
>
> . . .
>
> A. Again, it's specifically looking at the impact, is [adulterated product] out on the market?
>
> Q. Yeah.
>
> A. Yeah, I would seek additional expertise. (Bliesner Dep. at 101:10-102:14).[4]

Despite his admitted limits, and knowing of no methodology on which to base his opinion, Dr. Bliesner presses onward to testify that adulterated, and even out-of-specification

[4] This admission by itself establishes that Dr. Bliesner is not "qualified" to testify under Rule 702 because he lacks adequate knowledge, experience, training, or education to testify that Actavis released adulterated (much less, defective) Digitek® onto the market. Nothing in Dr. Bliesner's experience makes up for this shortcoming. He is trained as an analytical chemist and has no career experience analyzing Good Manufacturing Practices compliance outside a laboratory setting. (*See* Bliesner Dep. at 265:15-273:20). Nor has he ever worked as a Quality Assurance specialist in any context, and so he has no experience evaluating Quality Assurance systems or compliance. (*See id.* at 273:2-277:9). These are, however, the very areas that he purports to analyze as an expert in this case. (*See* Bliesner Report at 6).

tablets made it to consumers. (*See id.* at 214:24-215:13). His only basis for this conclusion appears to be a single e-mail indicating that in 2008, someone purportedly observed a double-thick tablet in a blister pack. (*See id.* at 57:17-58:1). But as Dr. Bliesner concedes (*see id.* at 64:1-65:25), and as Defendants explain in their Motion to Exclude Unreliable Hearsay, this observation is itself unreliable.

As for Dr. Bliesner's opinion that Actavis produced adulterated Digitek®, his expert report claims that he took the exact same approach towards this for-litigation opinion as he would outside the litigation context. He has not. He purports to treat Actavis the same as any of his other pharmaceutical company clients; that is, he "[a]ssumed Amide/Actavis was a new consulting client needing assistance with respect to determining their level of compliance with the CGMPs" and conducted a "Paper Audit" to conduct that analysis and determine Actavis's compliance status. (Bliesner Report at 6).

But the audit that Dr. Bliesner conducted for Actavis was far less rigorous than the audit Dr. Bliesner would conduct for a client. Dr. Bliesner has scarcely reviewed any production records—only a portion of the batch records for a few batches of Digitek®. (*See* Bliesner Dep. at 38:18-39:1). Instead, he primarily examined FDA regulatory documents, Actavis's response to those documents, deposition transcripts of "key personnel," the Digitek® ANDA, and various internal company e-mails and memoranda, hand-picked by Plaintiffs' counsel and not relating to any specific product. (*See* Bliesner Report at 6; Bliesner Dep. at 39:2-40:6). He skips steps, such as examining process-validation records, that he would comprehensively review in a non-litigation context. (*See* Bliesner Dep. at 40:17-41:15). And Dr. Bliesner performs this conclusory "audit" despite conceding during his deposition that he could not properly conduct an audit without examining production records:

Q. If a client hired you to assess its general GMP compliance.

A. Right.

Q. And said, I don't want to give you – I, client, don't want to give you access to the production records, you can do it from other records, could you properly do that?

A. If it was a – included an assessment of the production system?

Q. Yes.

A. No, you couldn't.

(*Id.* at 301:11-21). In fact, Dr. Bliesner would ordinarily tell a client that asked him to perform a comprehensive audit without full access to the production records that "they wouldn't be getting what they were asking for":

Q. Would you do an assessment if a potential client said no, we're not going to give you access to certain documents? Production records for example.

. . .

A. If it was to be a comprehensive review of compliance with the GMPs using a quality systems based approach, we would inform the client that unless we had access to those records, that they wouldn't be getting what they were asking for. (*Id.* at 299:20-300:16).

In short, Dr. Bliesner knows—and admits—that it is not possible to evaluate reliably whether a company produced adulterated product by merely looking at an FDA regulatory document and assuming its accuracy. He acknowledges that it is not possible, even for the FDA, to determine whether a compliance problem relates to a specific product without reviewing the actual production or batch records for that product. (*See id.* at 212:12-213:16). But that is *exactly* what he attempts to do here, rendering his adulterated product opinion unreliable.

Like Mr. Kenny and Mr. Farley, Dr. Bliesner applies a different and less intellectually rigorous methodology for his opinions in this litigation than he would for a pharmaceutical manufacturer client. His opinions too are inadmissible.

E. Russell Somma's Opinion That Actavis Released Out-of-Specification Digitek Is Impermissible "Ipse Dixit" Testimony.

Russell Somma's methodology differs from—and is even more unreliable than—the methods employed by Mr. Kenny, Mr. Farley, and Dr. Bliesner because he details an opinion beyond adulteration that Actavis released *out-of-specification* Digitek®. Dr. Somma's opinion is not the product of a reliable methodology; it is the product of no methodology at all. He has not conducted a comprehensive audit to support his opinions; he has reviewed only two batch records. (Somma Dep. at 36:6-9). His opinion's sole basis is "Russ Somma's Rule," which is nothing more than his personal hunch, a form of impermissible "ipse dixit" reasoning.

Dr. Somma admits that there is "no basis" for his opinion that extra-thick tablets were produced and released to market in any of the batches made before or after batch 70924 (the batch in which 20 double-thick tablets were identified and removed). (*Id.* at 211:11-23). The closest thing to evidence that he has seen is a report that "[t]here was one tablet in 2004, and that was it." (*Id.* at 252:2-253:3).[5] But even then, Dr. Somma concedes that large-scale production of out-of-specification tablets would likely be detected. (*See id.* at 107:13-108:14). Consequently, he admits that he has no opinion "to a probability" that out-of-specification tablets reached consumers. (*Id.* at 184:13-16).

Lacking evidence to support his opinions, Dr. Somma resorts to nothing more than a hunch, which he characterizes as "Russ Somma's Rule":

> Q. Do you have an opinion to a probability as to how many were made that were extra thick that were not detected?

---

[5] In fact, all of Plaintiffs' purported experts refer to this 2004 incident. That incident, however, occurred well outside the 2006-2008 recall period and, therefore, is not a reliable basis for an inference that recalled Digitek®, produced more than two years later, was out of specification. (*See* Background Statement at 20).

> A. I don't have a hard and fast rule, but my rule of thumb was if you see 20, you got a thousand. That's just Russ Somma's rule. Opinion, that's all.

(*Id.* at 208:4-9). If "Russ Somma's Rule" can be called a methodology at all, it falls well short of the *Daubert* reliability standard. It has never been validated by scientific studies, tested, or subjected to peer review. (*Id.* at 208:10-22). Its only basis is in Dr. Somma's experience that visual inspection is not accurate. (*Id.* at 208:13-15). Beyond that, it is unsupported speculation.

The Supreme Court instructs courts not to admit opinion testimony that is "connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146. But *ipse dixit* is all that Dr. Somma provides. His experience as a pharmaceutical scientist leads him not to a methodology, but to a hunch that if Actavis caught 20 extra-thick tablets in one lot, then there must have been more extra-thick tablets out there somewhere. At least Plaintiffs' other experts, Mr. Kenny, Mr. Farley, and Dr. Bliesner, *attempt* to apply a scientific method, lacking in intellectual rigor as their "audits" were. But Dr. Somma's unsupported opinion that Actavis produced and released not just adulterated, but out-of-specification, tablets is the worst sort of because-I-said-so testimony. His opinions must be excluded in order to prevent him from misleading a jury with his confident but baseless opinions.

F. Plaintiffs' Experts' Corporate Motive and Attitude Opinions Are Inadmissible.

All of Plaintiffs' experts are expected to offer inadmissible "bad company" testimony that Actavis was profit-motivated, had "sloppy" manufacturing practices, and was reckless with regard to consumer safety. Their reports offer a preview insofar as they contain passages characterizing Actavis's conduct and motives as representing a poor, even unethical corporate culture. For example, Mr. Kenny describes Actavis as "highly resistive to systemic change" and "arrogan[t]," and concludes that: "good people don't come to work with the intention of doing a

bad job. It is the company's misguided values, principles, and work-ethics (established by Actavis top management) that fostered bad behavior." (Kenny Report at 14, 35). Mr. Farley reports likewise that "[t]he problems at Actavis are systemic. That is, they are part of the actual operation of the company in its attitude and in its production of drugs for consumers." (Farley Report at 19). And Dr. Bliesner, for his part, blames Actavis for having a history of regulatory failures in part caused by a "lack of leadership and management controls at all levels within the organization." (Bliesner Report at 21).

None of Plaintiffs' experts may offer this sort of "bad company ethics" testimony because these sorts of opinions are beyond the scope of proper expert opinion. *See, e.g.*, *In re Trasylol.*, 2010 WL 1737107 at *9 (holding that plaintiffs' expert's opinions "fall outside the proper scope of expert testimony" because they contained "improper references to Bayer's and the FDA's knowledge and intent or are personal 'bad company' opinions not based on any FDA regulation or other applicable standard."); *Hines v. Wyeth*, No. 2:04–0690, 2011 WL 2680842, at *7 (S.D. W.Va. July 8, 2011) (excluding plaintiffs' expert's testimony regarding corporate state of mind and motive). Questions regarding corporate "intent or motive" are "classic jury question[s] and not one[s] for experts." *In re Trasylol*, 2010 WL 1737107 at *9 (citing *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004)); *see also In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (barring plaintiffs' expert from offering "a narrative of select regulatory events through the summary of selective quotation from internal [company] documents and "from testifying as to the knowledge, motivations, intent, state of mind, or purposes of [the company], its employees, the FDA, or FDA officials.").

Even if this Court refuses to exclude Plaintiffs' general liability experts in their entirety, it should at least limit Plaintiffs' experts from offering the sort of "bad company" testimony described above.

CONCLUSION

Unable to identify direct evidence of defect, Plaintiffs' general liability experts adopt the statements contained in an assortment of Plaintiff-selected regulatory documents as their own opinions. Those opinions—that Actavis released "adulterated" Digitek®—do not assist the fact finder in evaluating whether Plaintiffs satisfied their burden to prove defect. To embrace those opinions without any independent analysis—indeed, without reviewing those documents and the underlying data with the same thoroughness and "intellectual rigor" as they would in their ordinary profession—is inherently unreliable. And to use FDA documents as a springboard for an otherwise unsupported opinion that defective Digitek® reached consumers stretches the experts' chain of inferences beyond the snapping point, especially where each expert concedes that an adulterated drug is not the same as a defective drug. Consequently, their testimony is inadmissible under Rule 702 and their opinions should be excluded.

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CERTIFICATE OF SERVICE

I hereby certify that on August 3, 2011, a copy of the foregoing **MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' GENERAL LIABILITY EXPERTS** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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